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## **REMARKS**

### **Status of Claims**

Claims 1-26 and 28-37 are pending in this reissue application. Claim 27 has been cancelled.

### **Oath**

A supplemental oath will be filed as soon as possible.

### **Current Amendments to Claims**

Claim 25 has been amended to delete "at least." This amendment is supported by the specification's teaching of two chambers, which necessarily includes "at least" a first chamber. The amendment is being made for clarity, it being understood that the claim is a comprising claim that contains no limit on the number chambers. Claim 25 has further been amended to clarify the recitations in the final paragraph. This paragraph is presented under 35 USC 112, sixth paragraph, and should be construed to read on the disclosed access ports, which allow sterile transfer of fluids to or from the chambers, and equivalents. This amendment is clearly supported by the specification, e.g., column 3, at lines 50+.

Claim 28 has been amended by substituting the adjective "sterile" for "to maintain sterility." This is mostly for stylistic reasons and is supported by the specification at column 3, lines 50+. Claim 28 has also been amended by adding "said centrifuge comprises a locking element that selectively holds said container in said predetermined orientation" to recite a generic locking element. A locking plate 36 is disclosed in the specification, and this is adequate to disclose to one of ordinary skill in the art a generic locking element.

Claim 30 has been amended by replacing "further comprising" with "wherein said locking element comprises" to be consistent with claim 28. A locking plate 36 is disclosed in the specification.

Claim 32 has been amended by replacing "further comprising" with "said locking element comprises" and to add "movable locking" before "plate" to be consistent with claim 28. The locking plate 36 is clearly disclosed.

Claim 33 has been amended by reciting that the bridge is located at "top portions of" two chambers and to amend the recitation of access ports to provide that they are

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located near the tops of the chambers. Claim 33 has been further amended to recite an element covering an opening that allows sterile transfer through the opening. The specification discloses a "membrane," and it is submitted that this is adequate to disclose an "element" generically that allows sterile transfer to or from one of the chambers independently of the other of the chambers but may not be a "membrane."

#### Previous Amendments

For the sake of full compliance with the requirements of reissue applications, it is noted that (1) on September 10, 2001, claim 22 was amended in the third paragraph to change "have" to "has" (for grammatical reasons), claim 25 was amended in the second and third paragraphs to add the adjective "sterile" before "chamber," and claims 29 and 32 were amended (for grammatical reasons) to change "centrifuge rotor" to read "rotor of said centrifuge; (2) on July 15, 2002, claim 22 was amended to recite the feature of the holder wherein it receives and positions the container, it being clear from the specification that the holder at least partially allows the container to assume a predetermined position; and (3) on February 3, 2003, claims 22 and 25 were amended to recite that the first and second chambers are adjacent each other and that the fluid transfers from one chamber to another when the container is in a predetermined orientation; claim 22 was also amended to change "position" to "orient;" claim 25 was amended to add a recitation of "means for maintaining sterility during addition or removal of liquids." It is submitted that support for each of these amendments is clearly present in the original specification and drawings.

#### Rejections

The interviews with Examiner Cooley on August 19, 2003, December 19, 2003, and January 2, 2004, are noted. At the interview of August 19, 2003, the earlier rejections based on the prior art citations to McFarland, Crippa, and Onishi, were discussed. At the interview on December 19, 2003, the required format for amendments and the patentability of claims 25 and 33 were discussed. At the interview of January 2, 2004, the amendments made by this amendment were discussed, and it was agreed that further arguments made at the interview regarding claim 33 would be submitted. The essence of the arguments made in connection with the rejections is set forth below. Reconsideration of the rejections is respectfully requested.

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The reference to McFarland has nothing to do with the claimed invention and certainly does not show a container as claimed, which has a bridge connecting top portions of chambers to allow transfer of fluids between the chamber while also providing for sterile access to the upper parts of the chambers. McFarland shows a storage tank where fluids are introduced into the bottom parts of individual chambers and removed from those bottom parts. The upper parts receive air for forcing the fluids from the lower parts of the chambers. A connecting tube 32 allows air in one tube to ~~pass to another of the tubes, and even if one could argue that this is a bridge (which it is not)~~ there is certainly no teaching of the means for sterile transfer recited in claim 25 or the access ports recited in claim 33. Fluids in the McFarland device are only removed from the bottoms of the chambers and any removal from the top would require disassembly, which would destroy sterility. Further, no modification of McFarland to obtain the claimed invention would have been obvious to one of ordinary skill in the art mostly because McFarland is simply a storage tank, and any such modification would ruin it for its intended purposes. There is clearly no motivation to modify the McFarland storage tank to provide the claimed container.

In connection with claim 25, it is submitted that nothing in McFarland is equivalent to the recited means for sterile transfer of a liquid. MPEP §2183 sets forth four ways for assessing equivalence, and the claimed element differs from that shown in McFarland in all four ways. The function specified in claim 25 is that of "sterile transfer of a liquid to or from at least one of said chambers independently of the other of said chambers," and the corresponding structure disclosed is that of an access port with an opening that is covered by a membrane capable of receiving a syringe to inject or withdraw fluids. The structure shown in figures 1 and 2 of McFarland is simply a tubular connector 32, and in figure 3 is a header 62, neither of which allows introduction or withdrawal of fluids to at least one of the chambers independently of the other. Thus, McFarland fails to show structure capable of accomplishing the recited function. It is submitted further that neither the valve 34, nor the connector 32, nor the header 62 could be substituted for the structure disclosed in the instant application corresponding to the recited means. Application of the connector or header to the disclosed container would be nonsensical, and providing the storage tank of McFarland with the access

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ports designed to receive medical instruments such as syringes would completely ruin the McFarland storage tank for its intended purpose of pressurizing the tanks with air. Still further, it is submitted that there are substantial differences between the structure of McFarland that supplies connectors 32 and header 64, on the one hand, and the structure corresponding to the recited means, on the other, in that the McFarland structure is incapable of allowing transfer to or from one of the chambers independently of the others. Finally, the recited element is clearly not the structural equivalent of that shown in McFarland because they do not perform the same function and do not accomplish the same result.

Similarly, nothing in either Crippa or Onishi is equivalent to or would have led one of ordinary skill in the art to the invention. These containers are not designed to maintain sterility, and any addition or removal of fluids destroys sterility because the lids must be removed during the process. This contrasts significantly with the claimed subject matter where ports are provided for permitting sterile access to the chambers. Thus, the recited structures are not equivalent to the structures shown in Crippa and Onishi because the structures of Crippa and Onishi cannot perform the recited function of sterile transfer. For this reason they are clearly not interchangeable. There are clearly substantial differences between a lid that cannot maintain sterility and the recited structure that does. And, the lids of Crippa and Onishi are clearly not the structural equivalents of the recited structure because the Crippa and Onishi structures do not maintain sterility.

It is further submitted that no reference of record has the structure now recited in claim 33, or its equivalent, and that nothing in the references of record would have led one of ordinary skill in the art to the invention. McFarland, Crippa, and Onishi fail to show or suggest an access port with an element as claimed, and there is no motivation for one of ordinary skill in the art to modify the structures shown in any of these references to include such an access port.

Accordingly, it is submitted that this application is in condition for allowance, and an early indication thereof is respectfully requested. The examiner is invited to contact the undersigned if any matter remains outstanding.

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All necessary extensions of time are requested. Please charge any necessary fees and credit any excess to deposit account 50-1088.

Respectfully Submitted,  
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